Hellenic Accreditation System

Annex G1/7 to the Certificate No.**1255**-3

SCOPE of ACCREDITATION

of the

Private diagnostic clinical laboratory «MIKROSKOPISI»

Tested Materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Cytopathology Tests		
Conventional cervico-vaginal smears	Morphologic test - Detection and typing of pathologic lesions	Qualitative - semiquantitative method 1. Papanicolaou Stain 2. Automated Slide Stainer (Leica Autostainer XL) & automated Glass Coverslipper (Leica CV5030). 3. Microscopic evaluation 4. Reporting according to the BETHESDA 2014 System O.510-3/1/1-9-2019, O.510-4/1/1-9-2019
Cervico-vaginal smears, obtained by liquid based technique	Morphologic test - Detection and typing of pathologic lesions	Qualitative - semiquantitative method 1. Papanicolaou Stain 2. Liquid based cytology processor (THIN PREP CYTYC 2000)* 3. Microscopic evaluation 4. Reporting according to the BETHESDA 2014 system O.510-3/1/1-9-2019, O.510-4/1/1-9-2019
Cervico-vaginal smears, obtained by liquid based technique	Molecular assay for qualitative detection of 14 high-risk (HR) types of Human Papillomavirus. Molecular typing of HPV 16 and 18 and detection of other high-risk HPVs: 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.	Method CE-IVD Cobas 4800 HPV test. Performed according to the Kit Manufacturer's instructions (Roche Diagnostics) with automated nucleic acid extraction of the clinical sample on the COBAS x 4800 device and PCR reaction on the COBAS Z device.

** Commercial names mentioned are reffering to specific analytical method and laboratory work protocol.*

Site of assessment: **Laboratory permanent premises: 4 Thetidos & Michalokopoulou Str., Athens, 15128, Greece.**
Primary Sample Collection: **Laboratory permanent premises: 4 Thetidos & Michalokopoulou Str., Athens, 15128, Greece.**

Approved signatories: **A. Lainis, K. Savvidou, A. Diamantis, P. Nikolaou, A. Kelemtzi, O. Stamouli, D. Vasilakos.**

This Scope of Accreditation replaces the previous one dated 06.11.2025.
The Accreditation Certificate No. **1255**-3, to ELOT EN ISO 15189:2022, is valid until 10.05.2030.

Athens, 16th of September 2025

Konstantinou Evangelos Apostolos
CEO of ESYD